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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/000,005	SCHULER ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8-19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed April 6, 2005. The Examiner acknowledges the amendments to claims 1-4, 6 and 8-19; the cancellation of claims 5, 7 and 20; and the addition of new claims 21 and 22. Claims 1-4, 6, 8-19, 21 and 22 are pending.

Claim Objections

2. Claim 2 is objected to because of the following informalities: at line 1, "method claim1" apparently should read --method of claim 1--. Appropriate correction is required.

3. Claim 6 is objected to because of the following informalities: at lines 6-7, "said first waveform substantially corresponding to at least one of said collected waveforms" appears redundant in view of the limitation recited at lines 5-6 of the claim and apparently should be deleted. Appropriate correction is required.

4. Claim 16 is objected to because of the following informalities: at line 6, "waveforms" apparently should read --waveform--. Appropriate correction is required.

5. Claim 17 is objected to because of the following informalities: at line 2, --of-- apparently should be inserted following "step". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4, 16-19, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, provides support for transmitting a waveform selected from a plurality of collected waveforms to the body in order to regulate a body organ, but fails to disclose that the first waveform signal transmitted to the body to control organ function includes at least a second waveform that substantially corresponds to at least one of the collected waveforms and is operative in the regulation of the body organ.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-4, 6, 8-19, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 21 and 22, the step of transmitting recited in each claim requires that the first waveform *signal* includes a second waveform. There does not appear to be a first waveform recited prior to the recitation of the second waveform. Furthermore, it is unclear from

the claim language whether the first waveform signal is the same waveform as the second waveform, such that the recitation of a second waveform potentially fails to further limit the first waveform signal. It is indefinite whether the transmitting step is attempting to claim that a plurality of collected waveforms are being transmitted to the body or if a single waveform is being transmitted to the body where differing terminology is used to define the single waveform signal.

Claim 4 recites the limitations "the function" and "said connected waveforms" in line 3. There is insufficient antecedent basis for these limitations in the claim. There are no waveform functions or connected waveforms recited in the claims prior to these recitations.

Regarding claim 6, it is unclear how waveforms that are *indicative* of body organ functioning can be operative to stimulate or regulate a first body organ.

Claim 11 recites the limitation "said collecting means" in line 2. There is insufficient antecedent basis for this limitation in the claim. There are no collecting means recited in the claims prior to this recitation.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships involve how the digital to analog converter is structurally related to the other elements of the apparatus. More specifically, it is unclear whether the digital to analog converter converts the collected waveforms at the source of collected waveforms, the selecting means, the broadcasting means, or the sensor of claim 11.

Regarding claim 16, the claim recites that a first waveform signal is transmitted to the body, where the first waveform signal includes at least a second waveform signal. In view of this claim language, it is unclear whether the first waveform signal and the second waveform signal are the same waveform signals; whether one or more waveforms are being transmitted to the body; and if a plurality of waveforms are transmitted to the body, how the respective waveform signals differ from one another.

Claim 19 recites the limitation "the function performed by said waveform signals" in line 3. There is insufficient antecedent basis for this limitation in the claim. There are no waveform signal functions recited in the claims prior to this recitation.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-4, 6 and 8-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Humphrey ('239). Humphery teaches systems, methods and devices for stimulating and regulating body organ function, particularly in relation to paralyzed muscles of an arm (Figures 1, 10 and 11). The method includes collecting waveforms from the brain or nervous system that are representative of waveforms naturally occurring within a body from a body; at least

temporarily storing the collected waveforms in a storage medium of a computer processor (9); and transmitting a first waveform signal including at least a second waveform that *substantially corresponds to* one or more collected waveforms to the body organ to stimulate organ function. The collected waveforms are transformed from analog signals into a readable digital format for the computer processor. The collected waveforms are stored according to the function performed by the waveforms. The collected waveforms are transmitted to the paralyzed muscles through a stimulation controller that converts the digital signals to analog signals. The system includes a computer (9) forming a source of collected waveforms; means for transmitting at least one of the collected waveforms to a body organ; and means for applying the transmitted waveforms to the body organ. The transmitting means includes a digital to analog converter and the applying means can include a body electrode applied to the paralyzed muscles of the arm. The computer at least temporarily stores the waveforms in a digital format in separate storage areas (102) for collected waveforms of different functional categories. Recording electrodes (5) are placed on the body to collect the waveforms in analog form and transmit the waveforms to the computer source.

12. Claims 1, 6, 10-12, 15, 16, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy ('573). Kennedy teaches a system and method for stimulating and regulating body organ function. The method includes collecting waveforms from the brain or nervous system that are representative of waveforms naturally occurring within a body from a body; at least temporarily storing the collected waveforms in a storage medium (33); and transmitting a first waveform signal including at least a second waveform that *substantially*

corresponds to one or more collected waveforms to the nervous system to stimulate organ function. The system includes a source of collected waveforms (33); means for transmitting (22, 31) at least one of the collected waveforms to a body organ; and means for applying (30, 58) the transmitted waveforms to the body organ. Recording electrodes (30, 58) are placed on the body to collect the waveforms in analog form and transmit the waveforms to the storage medium.

Response to Arguments

13. Applicant's arguments filed April 6, 2005 have been fully considered but they are not persuasive.

Applicant contends that Humphrey does not teach or even suggest transmitting (or broadcasting) waveforms or waveform signals that include at least one waveform that substantially corresponds to a waveform that is produced by the body and is operative in the regulation of a target body organ. Applicant argues that Humphrey's collected waveforms are subjected to considerable processing and modification; and therefore, would thus not substantially correspond to a waveform (or waveform signal) produced by and collected from the body or include a signal representative of a signal produced by the body. The Examiner respectfully disagrees. There is nothing in the claim language that requires the transmitted waveforms or waveform signals be substantially identical to the collected, naturally-occurring waveforms. Moreover, there is nothing in the claim language that suggests the waveforms or waveform signals may not be processed or modified. The Examiner notes that the analog-to-digital conversion and digital-to-analog conversion of the collected waveforms in the present invention effectively comprises processing or modification of the waveforms, as well. Page 9,

lines 4-8 and 14-16, and page 10, lines 5-7, of the specification of the instant application further disclose processing and modification of the collected waveforms in the present invention. The Examiner respectfully submits that the claims only require that the transmitted waveform or waveform signal *substantially correspond to* at least one of the collected waveforms. Since the output waveform signal transmitted to the paralyzed limb is directly related to a given collected waveform in the Humphrey patent, the output signal can be considered to substantially correspond to the collected waveform.

Applicant finally contends that Humphrey does not teach or even suggest transmitting waveforms or waveform signals that are representative of waveforms that are produced by the body to (or through) the nervous system to regulate the function of a target body organ. The Examiner respectfully submits that claims 1-4, 6 and 8-19 do not require that the waveforms or waveform signals be transmitted to (or through) the nervous system.

In view of the foregoing, the rejection of claims 1-4, 6 and 8-19 under 35 U.S.C. 102(e) as being anticipated by Humphrey has been maintained.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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December 9, 2005